



DEPARTMENT OF HEALTH

GOVERNMENT RESPONSE TO THE REPORT FROM THE HOUSE OF COMMONS SCIENCE AND TECHNOLOGY COMMITTEE: GENETICS AND INSURANCE

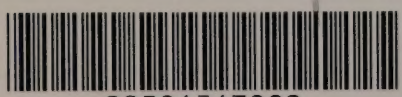
*Presented to Parliament by the Secretary of State for Health
By Command of Her Majesty
October 2001*



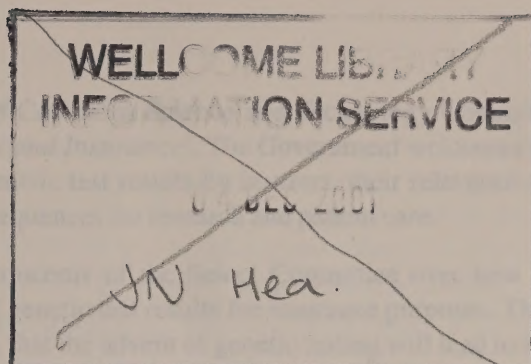
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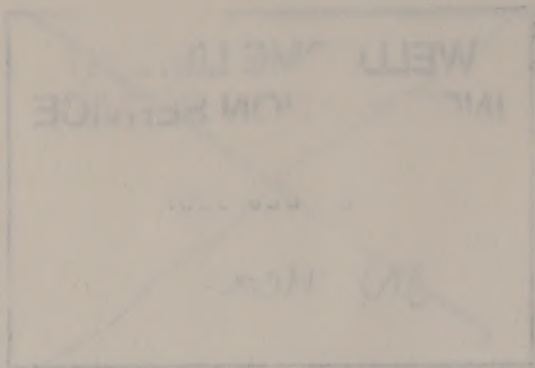
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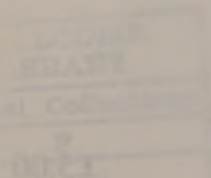
GOVERNMENT RESPONSE TO THE
REPORT FROM THE HOUSE OF
COMMONS SELECT COMMITTEE ON
TECHNIQUES AND GENETICS

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FOREWORD

In April this year the House of Commons Science and Technology Committee published a report on '*Genetics and Insurance*'. The Government welcomes this helpful review of the use of genetic test results by insurers, their relevance and reliability, and their wider consequences for research and patient care.

The Government shares the concerns of the Select Committee over how the industry has handled the use of genetic test results for insurance purposes. There are understandable public fears that the advent of genetic testing will lead to new forms of discrimination. The extent to which the public accept, demand or avoid genetic screening services in the future will depend in part on who will have access to genetic information. The Government considers it essential that people should not be deterred from taking a genetic test which could provide health benefits because they fear they may not be able to get insurance protection as a result. Similarly, individuals should not be deterred from taking part in genetic research because they fear the insurance consequences.

At the same time, the Government recognises the legitimate concerns of insurance companies over the consequences of 'adverse selection' where individuals with adverse test results take out larger than usual amounts of insurance cover in the expectation of an early claim and a substantial payout.

The Government has previously taken steps to ensure that any use of genetic tests by insurers should be based on sound evidence. The Genetics and Insurance Committee (GAIC) was set up in 1999 as an independent body with a remit to evaluate the genetic test results that insurance companies wished to use. The only test it has so far approved is for Huntington's Disease in the context of life insurance. The insurance industry has asked it to review a number of other tests and these applications are due for consideration over the next few months.

The Government has also been concerned to ensure that it receives effective advice on all aspects of genetics and the Human Genetics Commission (HGC) was established early last year. As one of its first tasks, it was asked to review the wider social and ethical implications of the use of genetic tests in insurance, as distinct from the technical issues covered by GAIC, and it published its interim recommendations in May this year. The Government welcomes the advice provided by the HGC in this area and has taken account of its recommendations in developing this response.

The UK insurance industry has long been aware of the concerns about the use of genetic test results for insurance purposes. The Association of British Insurers (ABI) has operated a Code of Practice setting industry wide standards for the use of such tests since 1997. This was the first such code in the world. The ABI had already undertaken to respect the decisions of GAIC and in May this year announced a voluntary moratorium on the use of all genetic test results for policies up to £300,000.

Following the recommendations of the Science and Technology Committee and the Human Genetics Commission, discussions have taken place between the Government and the ABI. As a result the ABI has now announced a new and stronger moratorium. The key features are:

- There will be a five year moratorium on the use of genetic test results by insurers
- The moratorium will apply to life insurance policies up to £500,000 and critical illness, long term care insurance and income protection up to £300,000 for each type of policy
- Over these limits, the insurance industry may use genetic test results but only where the tests have been approved by the Genetics and Insurance Committee
- There will be a review of the financial limits of the moratorium after 3 years

The ABI will continue to monitor member companies' compliance with its Code of Practice and the moratorium. However, the Government accepts the need for an independent mechanism to enforce the moratorium. We intend to review the membership of the Genetics and Insurance Committee and to extend its remit to give it an enhanced role in monitoring compliance with the moratorium. This will include taking up complaints from individuals who believe that an insurance company has failed to comply with the moratorium.

The Government recognises that the moratorium is unlikely to provide a permanent solution. However, we believe it will allow time to consider the implications of advances in genetic science and develop a policy that can be implemented for the longer term.

RESPONSE TO THE COMMITTEE'S RECOMMENDATIONS AND CONCLUSIONS

Paragraph 29: The insurance industry has failed to give clear and straightforward information about its policy on the use of genetic test results to the public, and appears to be uncertain itself about what exactly its policy is. We call on all insurance companies to publish a clear statement detailing exactly which genetic tests results they will consider (both positive and negative), for which conditions and under which circumstances, as soon as possible.

1. We share the concern of the Select Committee that the public has found the approach taken by insurance companies confusing. However the ABI has recently announced a new voluntary moratorium (October 2001) which clearly sets out the industry's agreed policy on the use of genetic test results by insurance companies. We welcome the ABI's proposal to make leaflets informing consumers about the moratorium widely available through patient interest groups, primary care and genetic testing centres.
2. The ABI has also undertaken to ensure that all information that member companies provide to the public reflects the terms of the moratorium and contains up to date information about which tests have been approved by the Genetics and Insurance Committee for use over the moratorium limits.
3. Some companies have chosen to go further than the moratorium and have already stated that they will not make use of any adverse test results. The Government welcomes this. We also call upon individual companies to publish clear statements as to whether they will use negative test results to negate the effect of a family history of a genetic condition when setting insurance premiums. We would expect that in most cases, confirmation by a geneticist of the relevance of the result will be required.
4. These provisions will ensure that consumers are able to make informed decisions with respect to their choice of insurer.

Paragraph 31: We acknowledge insurers' concerns about the risk of adverse selection and accept, as a principle, that commercial insurance companies should have access to the same information as applicants, where it is relevant and reliable – but only if there are no adverse consequences for society as a whole (for example, by discouraging people from taking tests).

5. The Government recognises that the current system of insurance contracts depends upon the disclosure of relevant information by both sides. However, the Government, like the Select Committee, also recognises that there may be adverse consequences for society if individuals are deterred from accessing a genetic test which may benefit their healthcare by fear of the possible consequences on their ability to obtain affordable insurance. The introduction of realistic ceilings on the use of genetic test results by insurers will allow individuals, for the duration of the moratorium, access to appropriate levels of cover while limiting the risk to the insurance industry from adverse selection in policies which are significantly larger than the average.

6. HGC is undertaking a wider review of the social and ethical consequences. The Government looks forward to receiving their report and recommendations in 2002.

Paragraph 32: It does not appear to be certain, at present, that the information obtained from positive genetic tests is relevant to the insurance industry.

Paragraph 33: The ABI's decision that four of the tests it recommended insurers use three years ago are now no longer relevant or reliable casts the gravest possible doubts on the validity of all the tests not explicitly approved by the GAIC, being currently used by insurers. Insurers have given the test results a predictive significance that cannot, at present, be justified.

7. The Government believes strongly that only tests that have passed scrutiny by the Genetics and Insurance Committee (GAIC) can be justifiably used by insurance companies. At present (October 2001) only one test has passed such scrutiny. We endorse the view expressed by the Select Committee that the use of other test results cannot be justified and welcome the ABI's moratorium making clear that only tests that have been through the complete GAIC review process can be used. The need for prior review by GAIC before any further tests are introduced for use in insurance risk assessment will provide a safeguard to consumers that results will only be used where there is adequate clinical and actuarial evidence of their predictive significance.

Paragraph 34: Insurers appear to have been far more interested in establishing their future right to use genetic test results in assessing premiums, than in whether or not they are reliable or relevant.

Paragraph 36: If the insurance industry wishes to reassure the public that they are acting in a reasonable manner, they must publish more data which unequivocally supports the changes made to insurance premiums based on positive genetic test results.

8. It is apparent from advice from the HGC as well as from the comments of the Select Committee that, with the exception of Huntington's Disease, few data have yet been published which support the use of genetic test results for insurance purposes.
9. Little of the actuarial research used to evaluate the effects of genetic conditions on insurance risk has been published in peer reviewed journals. The Government strongly encourages further high quality research in this area by insurers and actuaries and expects that this research will be subject to peer review and made publicly available.

Paragraph 37: We recommend that insurers should publish clear explanations as to exactly how such factors as early diagnosis and treatment are factored into their actuarial calculations.

10. Genetic testing will lead to earlier diagnosis and the development of new treatments. The impact of these disorders upon individuals' life expectancy and overall health will inevitably lessen even though this will take time to be reflected in published mortality statistics. It will be important for the industry to reassure the public as well as Government that such developments are properly reflected in the setting of premiums associated with a family history and adverse test results. Such developments are likely to have relevance in assessments of the actuarial relevance of genetic test results because of their potential impact on clinical outcomes for patients. GAIC will be asked to consider how best to incorporate into their review mechanisms up to date information on the benefits of early diagnosis and treatment.

Paragraph 38: We suggest that at present the very small number of cases involving genetic test results could allow insurers to ignore all genetic test results with relative impunity, allowing time to establish firmly their scientific and actuarial relevance.

Paragraph 39: The view of the ABI and some insurers, that ignoring genetic test results would be too costly, is contradicted by the actions of at least three insurance companies who have decided to ignore tests for the short-term and do not seem to regard it as an act of commercial suicide.

11. The introduction of higher financial ceilings in the new moratorium under which gene test results are disregarded means that the numbers of cases in which a gene test may still be relevant will be very small. The Government is aware of insurers' concerns about the risk of adverse selection and supports the continued assessment by GAIC of applications for the use of genetic test results for use in insurance above the ceilings of the moratorium.
12. A review has been built into the moratorium after three years. This will allow the industry to provide evidence of significant adverse selection, should it occur, and for the moratorium limits for each type of policy to be reviewed. It will also provide an opportunity for GAIC and HGC to review the working of the moratorium and whether the financial ceilings have proved to be sufficient in practice.

Paragraph 40: We welcome the policy of companies who take account only of negative test results in the calculation of premiums. The scientific and actuarial evidence currently available seems to indicate that this is the only justifiable use that can currently be made of genetic test results. We strongly recommend that the ABI and other insurers consider this when reviewing their policies.

Paragraph 41: We recommend that insurers explain publicly how they use family history information in the assessment of insurance premiums, and publish the supporting data.

13. Family histories can be taken into account by insurers when determining acceptance and/or the level of premiums. That practice is not covered by the moratorium. However, neither the terms of the moratorium nor the ABI Code of Practice preclude the use of a normal test result to reset the premiums to the population level where family history would indicate an increased premium. This provision is not restricted to tests which have been accepted as valid for use in insurance by GAIC.
14. It is also important to realise that the ABI moratorium represents a minimum position for its members. The Government welcomes the stance of individual companies who have stated that they are adopting policies more generous than the ABI position. It is essential that each individual company, including non-ABI members, makes the details of its policy available to allow consumers seeking insurance products to make an informed choice of provider.

Paragraph 45: If the use of tests by insurers is to be allowed, adequate research must be carried out to discern the impact of the use of genetic test results by insurance companies on the likelihood of patients seeking clinical advice. This research must be independent and have the confidence of all those involved but, as it is the insurers who wish to use the tests to protect their own interests, they should provide the funding.

Paragraph 47: The distinction between genetic tests carried out for purely research purposes and for diagnostic purposes must be clearly understood by all those who seek to use the results.

Paragraph 48: The statement by insurers and the ABI that they will never use results from genetic tests carried out for research purposes is extremely welcome. We recommend that this principle be incorporated into the ABI Code of Practice without delay.

15. The issue of the impact on healthcare and research remains a major concern for the Government and those providing healthcare to families with inherited disorders. It would be a serious matter if individuals were deterred from coming forward for testing that might be of benefit to them either as a diagnostic tool to inform their future healthcare or in the context of research.
16. The HGC has already commissioned research into the experience of those with serious and complex genetic conditions, but additional research would help reassure the public. The evidence that this is a significant issue is anecdotal at present but increasing publicity over insurance implications may make this more important. In this context we welcome the initiative of the ABI to provide leaflets explaining the effects of taking a genetic test on insurance which will be made available at genetic testing centres and to other appropriate healthcare providers to distribute to their patients.
17. The Government believes that the predicted health benefits which will be derived as a result of genetics research should not be jeopardised. The Government also welcomes the joint statement by the ABI, UK Forum for Genetics and Insurance and the British Society of Human Genetics which states that the results from genetic tests carried out for research purposes will not be used by insurers. This should be clearly covered in the ABI's revised Code of Practice.

Paragraph 52: The Government and the insurance industry must collaborate to provide an alternative form of insurance for those who would be denied it because of their genetic make-up. Alternative insurance arrangements may help to calm public fears about the risk of a genetic underclass.

18. The Government recognises the desire of many people to make provision for their families in the event that a change in their health or early death removes a main or major source of family income. The existence of the moratorium on the use of genetic test results means that taking a genetic test will not prejudice access to insurance unless the sum to be insured is unusually large.
19. There is concern that some of those who carry an inherited disorder may find insurance difficult to obtain because of their family history. The Secretary of State for Health has already stated that he will consult with genetic support groups and the insurance industry to examine what can be done to improve matters for those whose family history makes insurance difficult. The Government will continue to consider this during the moratorium period.

Paragraph 56: We believe that it is an unacceptable conflict of interests for a geneticist nominated by the ABI to judge his own test application, as a member of the GAIC.

Paragraph 57: We recommend that the membership of the GAIC should be thoroughly reconsidered if it is to inspire public confidence in its decisions.

20. GAIC is a specialist body with narrow terms of reference. Its remit is to assess whether there is scientific and statistical justification for the results from a particular genetic test to be used by insurance companies.
21. GAIC has a membership appointed by Health Ministers comprising three major groups – the industry, patient representatives and clinicians. All members have equal status and the Committee reaches its decisions by consensus.
22. The geneticist nominated by the ABI has provided invaluable expertise to GAIC. It should be noted that this member was appointed prior to his involvement in the preparation of applications to the committee. The Government is satisfied that a conflict of interest has both arisen and been properly declared in accordance with OCPA guidance.
23. Nevertheless the Government recognises that there remains a perceived conflict of interest in having the ABI's genetics adviser continuing his membership of GAIC and notes that Professor Raeburn has decided to step down from the Committee.
24. Based on experience to date, GAIC itself has recognised the need for extension of the membership. It has recommended that there should be two members with expertise in each of the key areas of clinical genetics, insurance practice, patient/consumer perspective and the actuarial profession. It also recommends that the committee would be strengthened by the appointment of additional members including a member with expertise in consumer affairs, an insurance broker and a genetic nurse counsellor.

25. The present membership of GAIC is due for review no later than April 2002. The Government notes the concerns of the Select Committee and proposes to appoint new members to extend the committee membership as suggested by GAIC and will bring forward the appointments timetable with immediate effect.
26. The expertise gained by the existing members over the last two years has been very valuable and the significance of the contribution made by the existing members to the consideration of the use of specific genetic tests is fully recognised. It is envisaged that several members of the existing committee may be invited to serve a further term of office in order to retain this expertise.

Paragraph 58: We recommend that the reformed GAIC re-examine the decision to approve the use of the Huntington's Chorea genetic test for use by insurers, with extensive peer review both for the data supplied by insurers and its own decisions, prior to publication.

27. Following review by independent expert clinical geneticist and actuarial reviewers, the data submitted to GAIC were considered sufficient by all of the Committee members to enable it to reach a decision by consensus on the issue of Huntington's Disease test results for life insurance policies.
28. GAIC recognises that there are three conditions that need to be met before a test can be deemed to be suitable for use when assessing insurance proposals:
 - Is the test technically reliable? Does it accurately detect the specific changes sought for the named condition? This is the *technical relevance* of the test.
 - Does a positive result in the test have any implications for the health of the individual? This is the *clinical relevance* of the test.
 - Do the health implications make any difference to the likelihood of a claim under the proposed insurance product? This is the *actuarial relevance* of the test.

Only where all three of these conditions are satisfied can a test be approved by GAIC for consideration by the insurance industry in setting premiums for insurance.

29. The Government considers that these criteria are appropriate to assess proposals for the use of genetic test results. However, we recognise that in the light of experience the detail of how these are assessed may need revisiting. Indeed, GAIC has already started to reconsider its criteria in the light of experience in assessing the first test. When additional members are appointed to the committee, the Government believes that it will be important for the new committee to revisit the detailed criteria for assessment of applications in order that the whole committee is cognisant of and supports the process to be used. It is possible that at this time, the decision of the committee on the use of test for Huntington's disease in life insurance may need to be revisited in the light of their conclusions.

Paragraph 59: The GAIC should be given the ability to approve the use of negative test results alone for use by insurers, without allowing the use of positive results.

Paragraph 59: We recommend that some mechanism be established to facilitate applications for the approval of tests by the GAIC, from bodies other than insurers.

30. The terms of reference of GAIC do not preclude the committee looking at proposals from sources other than the industry, nor from approving the use of a particular type of result where data supports its relevance to an insurance product. However, some insurers are already using the results of tests which show that a person is not at increased risk of a genetic condition to negate the effect of a family history of a genetic condition when setting an insurance premium. The Government envisages that this will continue. It is where the insurer wishes to use an adverse test result to justify less favourable treatment of an individual that the scrutiny of GAIC becomes important. This is to ensure that people are not unfairly discriminated against because of their genetic inheritance.
31. Where an individual with a known family history of a particular genetic condition has had a negative test result the Government considers that insurers should take the negative test result into account. We would expect that in most cases, confirmation by a geneticist of the relevance of the result will be required.

Paragraph 60: It is imperative that the GAIC be properly resourced for the work it is doing.

32. Although GAIC's resources to date have been adequate to meet the committee's remit the Government accepts the need to keep this issue under review.

Paragraph 62: The previous unwillingness of Government to become involved in this area has contributed to the atmosphere of confusion and ignorance that pervades the use of genetic test results.

33. Since 1997, the Government has been actively involved in developing a system of oversight of all areas of human genetics. No less than three advisory bodies have been asked to make recommendations to help develop policy on the specific issue of genetics and insurance.
34. In December 1997 the Government established the Human Genetics Advisory Commission as a non-statutory body to report to UK Health and Industry Ministers on issues arising from developments in human genetics. At one of its early meetings HGAC identified genetic testing and insurance as one of the first areas on which it would work. Following a consultation exercise, the HGAC produced a report in December 1997 on *'The implications of genetic testing for insurance'*. The Government issued a response to the HGAC's recommendations in November 1998.

35. The Government agreed with the HGAC's conclusion that a permanent ban on the use of genetic test results by insurers would not be appropriate. However the Government accepted the need for an independent mechanism to evaluate the reliability and actuarial evidence relating to the use of specific genetic test results by insurers. The Government acted quickly and by April 1999 a new body, the Genetics and Insurance Committee (GAIC) had already started work.
36. A major review of the mechanisms for providing Government with advice on all aspects of genetics, led to the establishment in 2000 of a new advisory body in human genetics, the Human Genetics Commission, to replace the HGAC. Recognising the widespread public concern over genetics and insurance, the Government specifically asked the Human Genetics Commission to look into this issue as part of its first workplan.
37. As well as these formal mechanisms there have been regular meetings between the insurance industry and the Department of Health, Office of Science and Technology and the Treasury at official and Ministerial level to make progress on this subject.

Paragraph 64: There must be doubts whether the ABI, a trade organisation funded by insurers to represent their own interests, is the right body to regulate the use of genetic test results.

Paragraph 65: The ABI must act as a matter of urgency to convince the Government and the public that the Code of Practice is being complied with.

Paragraph 66: Insurers must prove that they are capable of regulating themselves effectively and thoroughly, with sanctions in place to ensure compliance. The ABI's Code of Practice is a welcome step in the right direction by insurers but it is inadequate in its present form. The reformed GAIC should make recommendations to the ABI for its Code of Practice. The GAIC should also closely monitor insurers' compliance with the Code.

38. Following the introduction of a stronger moratorium the ABI has stated its intention to revise its Code of Practice. The Government welcomes the fact that the ABI has agreed to consult with interested bodies including the British Society for Human Genetics, HGC and GAIC on the preparation of the revised Code of Practice.
39. The Government believes that there should also be independent oversight of the use of genetic tests by insurers. To achieve this we propose that the role of the Genetics and Insurance Committee should be expanded to provide more wide ranging oversight of how insurers are using genetic tests approved by GAIC. GAIC will also be asked to provide independent scrutiny of compliance with the Code and moratorium. This process will include requiring regular returns from insurers and also asking patient groups such as the Genetic Interest Group and also GPs and regional genetics centres to report any instances where the ABI Code does not appear to have been followed.

40. If an insurance policy applicant is unhappy about the way an insurance company has dealt with their application under the moratorium, under the new arrangements they should take the matter up with their insurance company in the first instance. If they are not satisfied with the result they will be encouraged to contact the ABI. If the applicant remains dissatisfied they will be able to take their complaint to GAIC. If GAIC cannot resolve the matter an independent tribunal will be set up as set out in the ABI Code of Practice. This tribunal has wide ranging powers including the provision to impose unlimited fines.
41. GAIC will be asked to make annual reports to Ministers on compliance by insurers with the moratorium and Code of Practice.

Paragraph 67: Insurance companies were wrong to use the results of genetic tests in assessing risk before they had been approved by the GAIC. We recommend that all insurance companies should immediately cease to use the positive results from any genetic test that has not been explicitly approved by the GAIC.

Paragraph 68: The insurance industry would certainly benefit from concentrating efforts on building public confidence in its actions and motives, rather than giving itself the right to extend its ability to load premiums.

42. The Government agrees with these recommendations from the Select Committee. As part of its moratorium announcement on 1 May, the ABI has made clear to its members that this practice should now cease. Further measures have since been taken to clarify the information which should be placed on insurance application forms and companies' web sites on this issue. Any failure of this agreement may lead to reconsideration of the Government's position regarding the need for statutory control.

Paragraph 70: We do not believe that legislation denying insurers access to all genetic test results would be appropriate.

Paragraph 71: The best way forward for the Government and industry would be a voluntary moratorium on the use of all positive genetic test results by insurers for at least the next two years. During this time more research should be done to establish the actuarial and scientific relevance of genetic test results to the assessment of premiums, and the possible consequences for research and healthcare. If the insurers are unable, or unwilling, to regulate themselves and enforce this moratorium, we recommend that Government enforce its will by legislation. We further recommend that insurers should still consider negative test results in assessing insurance applications throughout any moratorium.

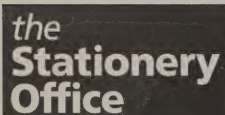
Paragraph 72: It would be better for the insurance industry to act responsibly now, rather than be forced into a commercially compromised position in the future.

43. The Government agrees that legislation denying insurers access to all genetic test results would be inappropriate.
44. The Government has discussed the scope of the voluntary moratorium with the ABI. It has been agreed that ABI will extend their voluntary moratorium to £500,000 for life insurance and £300,000 for other types of policies. These limits cover a single category of insurance, e.g. the total of an individual's life policies, rather than individual policies or a complete portfolio. The moratorium will stand for a period of 5 years, unless a long-term policy can be agreed and implemented sooner, with provision for review of the financial limits after an initial 3-year period. The Government welcomes the willingness of the insurance industry to extend their moratorium in this way.
45. During the moratorium, the Government will be working with the industry, patient groups and other stakeholders, to formulate and agree a longer-term policy. The consideration of results of further research into the actuarial and scientific relevance of genetic test results to the assessment of premiums, and the possible consequences for research and healthcare, will be important in informing this policy.
46. If there is evidence of serious and persistent non-compliance with the moratorium by the insurance industry, then the Government is prepared to enforce the moratorium, through legislation if necessary.

Paragraph 73: We strongly recommend that the HGC should continue to monitor the use of genetic test results by insurers and the consequences of their actions, in their widest possible context, and advise Government on further developments as they arise and in a timely manner.

Paragraph 74: The HGC's programme and, in particular its efforts to involve as many of the public as possible in its consultations, should not be undermined by a lack of resources. The Government should, as a matter of urgency, review the funding and resources the HGC is allocated. If the HGC is to receive extra work as a result of our recommendations, this should also be reflected in its budget.

47. The Government agrees with the Select Committee that the HGC has an important and valuable role to play in this area. The Government welcomed HGC's interim recommendations on genetic testing and insurance and has taken account of them in producing this response. The HGC will continue to consider the issue during the moratorium period and the Government will expect the new GAIC to consult the HGC where appropriate.
48. The Government is committed to keeping the resources available to all of its advisory bodies under review. HGC is seen by Government as an important safeguard which helps ensure that wider social and ethical aspects of developments in genetics are properly considered and publicly debated.



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